InterStim® Therapy: A Contemporary Approach to Overactive Bladder

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Overactive bladder is a common and challenging condition for the practicing obstetrician-gynecologist. The prevalence of the condition is increasing with our aging population. Although some patients respond to first-line therapy, a significant number will require sacral nerve stimulation to address the underlying neurologic condition that causes overactive bladder as well as other pelvic floor conditions. This article summarizes the epidemiology and symptomatology, office evaluation, and treatment of overactive bladder with particular emphasis on sacral nerve stimulation (SNS). SNS technique, results, and future applications are also reviewed.
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Overactive bladder syndrome (OAB) is an increasingly common condition presenting to the obstetrician-gynecologist (ob-gyn) due to the aging of our population, increasing patient awareness through physician counseling and mainstream media exposure, improved understanding of the condition, introduction of new treatment modalities, and an increasing desire for quality-of-life improvement. Despite the introduction of effective treatment modalities over the past decade, including multiple newer anticholinergic agents and sacral nerve stimulation, the condition continues to be undertreated by most physicians. This may be due to lack of general knowledge among clinicians regarding the

condition, inability to formulate a time-efficient and cost-effective diagnostic algorithm, and confusion over which treatment is most appropriate. Most patients can be easily and effectively treated by the ob-gyn in the office setting; few may require subspecialty referral. Most clinicians are familiar with pharmacotherapy used for first-line treatment of overactive bladder, but few appreciate or understand sacral nerve stimulation as an alternative treatment modality, especially for those patients unable to tolerate or refractory to traditional anticholinergic medication. This article provides a basic overview of overactive bladder, presents a sample diagnostic algorithm, and discusses treatment modalities with particular focus on sacral neurostimulation.

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Epidemiology of OAB

Previously referred to as *urge incontinence* or *detrusor instability*, the term *overactive bladder syndrome* adopted by the International Continence Society (ICS) provides a more comprehensive and descriptive approach to the condition. Overactive bladder is defined by the ICS as urgency, with or without urge incontinence, usually with frequency and nocturia in the absence of local or metabolic factors explaining these symptoms.[1] They define *urgency* as the sudden compelling desire to pass urine that is difficult to defer and *urge urinary incontinence* as involuntary leakage accompanied by or immediately preceded by urgency.[1] Other important ICS terms include *daytime frequency* (the patient considers that she voids too often by day) and *nocturia* (the patient has to wake once or more at night to void).[1]

The exact prevalence of OAB is unknown as authors use different definitions of OAB in epidemiologic studies and clinical trials. The EPIC study is the largest population-based survey to assess the prevalence of OAB using the 2002 ICS definitions of urinary incontinence (UI), OAB, and other lower urinary tract symptoms (LUTS) in men and women.[2] It was conducted between April and December 2005 in Canada, Germany, Italy, Sweden, and the United Kingdom via computer-assisted telephone interviews of a random sample of adult men and women. They found that of the 19,165 subjects, 64.3% reported at least 1 LUTS. The most prevalent symptom was nocturia (men, 48.6%; women, 54.5%). Overall, 1434 subjects (11.8%) were classified as having OAB (502 men, 932 women). OAB was more prevalent than all types of urinary incontinence combined (9.4%).[2] Among the subjects defined as having OAB, the most prevalent combination of symptoms was nocturia and urgency.[3] Urgency combined with 3 or more LUTS was reported in the majority of subjects defined as having OAB and the number of LUTS increased with increasing age.[3]

Over 33 million adults may suffer from overactive bladder syndrome.

In the United States, the National Overactive Bladder Evaluation (NOBLE) study estimated overall OAB prevalence and differences between OAB populations.[4] Based on a computer-aided telephone survey of 5204 adult subjects, the overall prevalence of OAB was noted as 16.9% in women and 16.0% in men.[4] Similar to the EPIC study, the prevalence of OAB rose with increasing age. The NOBLE study also differentiated OAB as OAB wet (with incontinence) or OAB dry (without incontinence). They defined *OAB dry* as 4 or more episodes of urgency in the previous 4 weeks, with frequency of greater than 8 times per day or the use of 1 or more coping behaviors to control bladder function. The overall prevalence of OAB from that study was 16.9% in women and 16.0% in men. Extrapolated to the US population, over 33 million adults may suffer from OAB. More importantly, only one-third of the respondents had associated urge incontinence, whereas the remaining two-thirds were classified as OAB dry. This is an important point, as the commonly asked question, "Do you have any problem with urinary leakage?" might not capture the majority of patients with clinically significant OAB symptoms such as sensory urgency, daytime frequency, and nocturia. The prevalence of OAB symptoms increased with age in both men and women, rising from less than 10% in the 25- to 34-year-old age group to 30% in the greater than 75-year-old age group. Notably, the prevalence of OAB wet in women increased from 12% at age 60 to 20% at age 65 years or older.[4] This is important to note because at younger ages, incontinence may not significantly impact quality of life.

In 2002, Dmochowski and Newman conducted an online survey of 1228 women aged 40 to 65 years to assess the impact of OAB and patient satisfaction with treatment.[5] They categorized the subjects as no OAB (control group, n = 330) or OAB symptoms (n = 898). The subjects with OAB symptoms were further subdivided into treatment groups:

current users of OAB prescription medications (n = 309), lapsed users of OAB prescription medications (n = 265), and those who have never been treated (n = 324). They found that OAB symptoms significantly affected self-esteem, family and sexual relations, lifestyle, professional life, and health perception. Of those women who did discuss OAB symptoms with a health care provider, more than half waited at least 1 year to request treatment. They also found that many health care providers do not screen for OAB. Most women expressed dissatisfaction with currently available OAB treatments and their side effects.[5]

Office Evaluation of OAB

Diagnosis of OAB is made in the office through patient history, physical examination, and basic bladder testing. Complicated patients may require subspecialty referral to urology or urogynecology prior to initiating treatment. Complicated patients include those with prior prolapse surgery, prior radical pelvic surgery, history of pelvic radiation, advanced prolapse, incomplete bladder emptying, recurrent urinary tract infections, hematuria, or unclear diagnosis (Table 1). In most cases, treatment can often be started by the generalist after 1 or 2 office visits.

Patient Tools

There are several validated questionnaires available to help assess patient symptoms prior to their first office visit. Clinicians treating overactive bladder and urinary incontinence are encouraged to consider these tools as part of their intake forms when obtaining a patient history. The short-form Incontinence Impact Questionnaire (IIQ-7) is a 7-question tool that helps determine type of incontinence and its effect on social relationships, independence, and emotional health.[6] There is also a shorter tool available, 3 Incontinence Questions (3IQ), that helps differentiate urge and stress incontinence. The 3IQ has been shown to be 75% sensitive and 77% specific in diagnosing urge incontinence.[7] In addition, the Overactive Bladder Validated 8-Question Screener (OAB-V8) is designed to assess the impact of OAB on a patient-based bother scale.[8]

Prior to the first visit, it may be useful to have the patient complete a 2-day voiding diary. This is a self-administered diary completed by the patient for 2 24-hour periods, which do not have to be successive. The patient keeps track of all fluid intake, including type of fluid (specifically alcoholic or caffeinated beverages), timing, and volume. She also records all voids and volumes using a voiding hat. The tool can additionally be used to assess incontinence. The patient records all incontinent episodes including timing, activity during episode suggesting stress incontinence, presence of urge, and approximate volume of leak. Patients with OAB will usually demonstrate frequent small-volume voids. They may be overconsuming liquids, specifically those that are known bladder irritants (caffeine and alcohol). Women with OAB wet may also demonstrate large volume leaks associated with urge. The bladder diary is an excellent tool to assess patient complaints and correlate them with objective data. It will also help differentiate between those patients having high-frequency/high-volume voids, often due to increased fluid intake, from those having high-frequency/low-volume voids, consistent with OAB. It may also be used for follow-up comparison after a treatment regimen has been started.

Table 1
Indication for Subspecialty Referral

Unsuccessful prior surgery	Radical pelvic surgery
Concurrent neurologic condition	Unclear diagnosis
Advanced prolapse	Difficulty in emptying
Prior prolapse surgery	Hematuria
Recurrent urinary tract infection	

Patient History

A thorough history is invaluable for the proper diagnosis of OAB. The patient should be questioned about the duration, severity, and type of OAB symptoms experienced, as well as how much they impact daily activities. Any urinary incontinence, whether associated with urge or stress, should be discussed. Voiding patterns should be reviewed as many patients void frequently to keep their bladder volumes low in an attempt to avoid or minimize the impact of their stress or overflow incontinence.

A complete medical and surgical history should be obtained with special attention to previous incontinence/prolapse surgery. Several coexisting medical conditions may also influence OAB, including diabetes, other endocrine abnormalities, neurologic disease, sleep apnea, or history of back injury. Medications should be reviewed as diuretics, antihypertensives, antidepressants, and antipsychotic

medications can all have urinary side effects. A baseline validated questionnaire such as those already discussed may also be helpful.

Physical Examination

A complete physical examination, including abdominal and pelvic examination, should be conducted at the first visit. Basic neurologic evaluation including lower extremity deep tendon reflexes, assessment of perineal sensation, and evaluation of the anal and clitoral reflexes is helpful, especially in patients with suspected neurologic disease. The pelvic examination should include full visual inspection of the vaginal and external genitalia as well as speculum and bimanual examination. While examining the perineum, the physician should pay attention to estrogenization of the tissues as well as look for signs of irritation from chronic urinary incontinence. Vaginal examination should include visualization and palpation. Prolapse is best assessed with a half speculum used to retract the posterior wall to assess for signs of suburethral mass or cystocele. The patient should be examined at rest and with Valsalva maneuver. Significant cystocele causing bladder outlet obstruction can be associated with OAB. The half speculum can then be used to visualize the posterior vaginal wall and assess for rectocele and enterocele. A bimanual examination should then be performed to assess uterine size. Careful attention should be paid to the presence of any suburethral mass consistent with urethral diverticulum on digital palpation. If the patient has any complaints of urinary incontinence, a cotton swab test of urethral hypermobility may also be performed.

Bladder Testing

Simple bladder testing is easily performed at the initial office visit and helps to formulate a diagnosis and appropriate treatment plan. This routinely involves a urinalysis and urine culture to rule out infection and a postvoid residual volume measured via bladder scanner or urethral catheterization. Further testing, including simple cystometrogram (CMG) and uroflow, can also be easily performed in the office. Complex uroflow may be performed with a full bladder before or after simple CMG and does require special equipment. The patient is asked to come to the office with a full bladder for uroflow. She then voids on a special commode that records volume voided, maximum flow rate, average flow rate, time to maximum flow, and voiding time. A postvoid residual volume is then measured via bladder scanner or urethral catheterization. Simple CMG may then be performed. The bladder is catheterized to check postvoid residual volume and a urine specimen is sent for urine culture and/or cytology as indicated. A 50-mL syringe with the plunger removed is attached to the urethral catheter. Sterile water or saline is then used to slowly backfill the patient's bladder. During backfill, the patient is asked questions to determine first urge to void, normal urge to void, urgent need to void, and maximum bladder capacity. The patient is not filled beyond 500 mL to avoid ureteral reflux. At maximum capacity, the patient is asked to cough (with prolapse reduced if present) in lithotomy position as well as standing. This will demonstrate any stress urinary incontinence. Patients with OAB typically demonstrate smaller bladder capacity (normal is 400-600 mL) and may also demonstrate detrusor overactivity during fill. This is objectively seen by increases in the level of fluid in the syringe during filling. She may also demonstrate large volumes of leakage during filling or when moving from lithotomy to standing positions.

Urodynamic testing and cystoscopy are usually performed by urology or urogynecology subspecialists. These tests are not required for first-line evaluation of OAB. Multichannel urodynamic testing requires special equipment and training. It allows precise measurement or calculation of intraurethral, intravesical, and intra-abdominal pressures during filling and emptying of the bladder. Most patients with OAB will demonstrate reduced maximum bladder capacity and early sensations on testing. Some will show spontaneous detrusor contractions and reduced compliance during filling. Cystoscopy is usually normal in OAB patients. In some patients it may show trabeculations, stones, or abnormal masses or lesions associated with bladder cancer.

First-Line OAB Treatment

Treatment of overactive bladder is relatively straightforward and clinicians may benefit from following a regimented treatment algorithm as suggested in Figure 1. Initial treatment of the uncomplicated patient begins with a conservative protocol consisting of bladder retraining, pelvic floor exercises, dietary modification, and anticholinergic medication. Bladder retraining requires the patient to void at increasing intervals on a weekly basis, thereby improving bladder volume and decreasing spasms over time. Pelvic floor exercises can help both stress incontinence and OAB and are best taught to the patient with simple biofeedback techniques during a vaginal examination. A finger is placed in the vagina and the patient is asked to squeeze the pelvic muscles. Proper recruitment of pelvic floor muscles and baseline tone can easily be assessed. Those patients unable to properly contract the pelvic floor muscles may be good candidates for pelvic floor physical therapy referral. Dietary modification includes

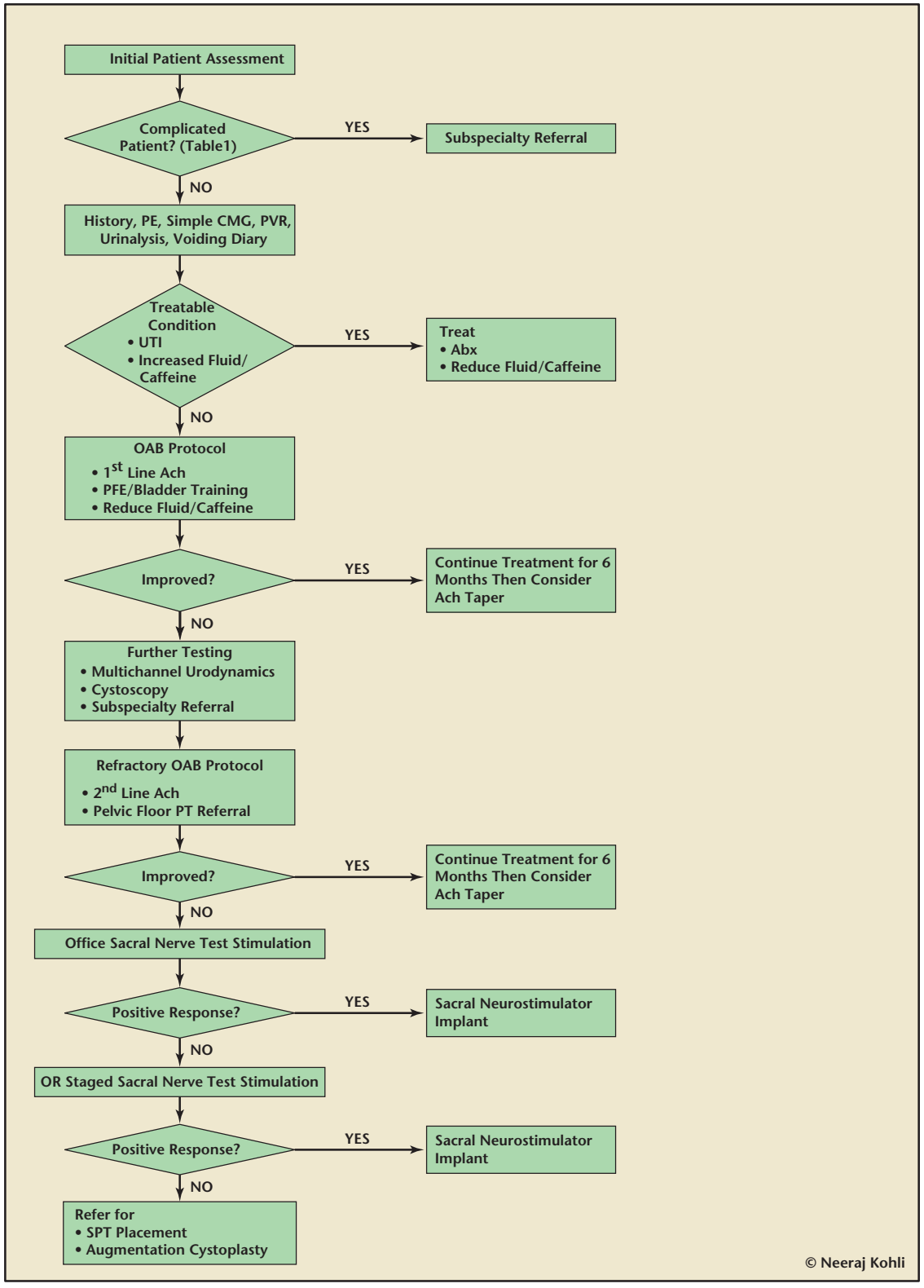

Figure 1. *Overactive bladder syndrome treatment algorithm. Abx, antibiotics; Ach, anticholinergic; CMG, cystometrogram; OAB, overactive bladder syndrome; OR, operating room; PE, physical examination; PFE, pelvic floor exercises; PT, physical therapy; PVR, postvoid residual volume; SPT, suprapubic tube; UTI, urinary tract infection.*

reduction of fluid intake, caffeine, and other bladder irritants.

Pharmacotherapy has long been the mainstay for treatment of OAB and a variety of newer drugs have recently been introduced (Table 2). These drugs are anticholinergic muscarinic receptor antagonists and have demonstrated comparable efficacy with varying dosing schedules, side-effect profiles, and biochemical properties. Compared with placebo, studies have shown anticholinergic medications to be effective in reducing frequency of micturition, sensory urgency, and episodes of the urge incontinence. In a study of solifenacin, it was noted that 51% of patients taking 5 mg of the drug reported resolution of their urge incontinence versus 38% for placebo.[9] Other anticholinergic medications have reported similar results. In an open-label, flexible dose study in those patients previously treated with tolterodine, solifenacin was noted to produce significant improvement in most test parameters including urgency, frequency, and urinary incontinence as well as changes in all OAB questionnaire scales and domains (symptom bother, coping, concern, sleep, social interaction, and total health-related quality of life). Unfortunately, anticholinergic medications may produce significant side effects due to blockade of M3 and other muscarinic receptors (M1-M5) in various other parts of the body, including the salivary glands, gastrointestinal tract, eyes, brain, and heart. Side effects can include dry mouth, constipation, dry eyes, memory loss, and heart palpitations. In the same solifenacin study, treatment-emergent side effects characterized as mild or moderate occurred in 90.8%, but led to few discontinuations (3.6%). Anticholinergic side effects included dry mouth (17.5%), constipation (11.6%), and blurred vision (2.3%).[9] Studies assessing other anticholinergic agents have shown similar efficacy and side effects.

Gopal and colleagues[10] studied the discontinuation rates of patients treated with anticholinergic medication secondary to poor tolerability or suboptimal success rates using a large database search. They analyzed 49,419 episodes of anticholinergic therapy initiated in 29,369 women. The average number of treatment episodes and number of drug classes prescribed per patient were 1.65 ± 1.31 and 1.54 ± 0.57, respectively. The median time for overall anticholinergic drug discontinuation was 4.76 months. The 6-month unadjusted cumulative incidence of discontinuation was 58.8%. The percentage of episodes in which women switched to another medication was 15.8%. Discontinuation rates ranged from 54% to 71% depending on the medication used, with oxybutynin having the highest rate among those drugs studied.[10] It should be noted that previous placebo-controlled trials of anticholinergic medications have also noted a high withdrawal rate in the placebo group during the study. Although anticholinergic medication may help some patients, recent studies have shown long-term compliance is suboptimal due to variable success rates and poor tolerability. In those patients who did not respond to initial

Table 2
Drugs Available for Overactive Bladder Syndrome

Generic Name	Trade Name(s)	Daily Dosage	Special Consideration
Oxybutynin	Oxybutynin	5 mg bid-qd	Generic available at low cost; high incidence of dose-related side effects
	Ditropan XL®	5 mg, 10 mg, 15 mg qd	
	Oxytrol®	3.9 mg twice a week	Convenient dosage able to titrate; high incidence of side effects
			Transdermal system avoids first-pass effect; decreased side effects; skin irritation; increase of efficacy of oxybutynin
Tolterodine	Detrol® LA	4 mg qd	Longest experience/large amount of data; no titration dose
Solifenacin	VESIcare®	5 mg, 10 mg qd	Long half-life; high compliance rate
Darifenacin	Enablex®	7.5 mg, 15 mg qd	M3 selective; decrease in cardiac/cognitive side effects
Trospium Chloride	Sanctura XR™	20 mg bid	Renal metabolism with decreased drug interaction; local bladder effect; bid dosing

anticholinergic treatment, dose escalation or alternative anticholinergic medication is recommended. If the patient does not have significant improvement or is having significant side effects after 2 or more anticholinergic agents have been adequately tried (>2 months each), further evaluation, including multichannel urodynamic testing, and treatment options, including pelvic floor physical therapy referral or sacral nerve stimulation, is recommended. Patients with underlying neurologic conditions, coexisting voiding dysfunction, incomplete bladder emptying, or markedly reduced bladder capacity with obvious bladder spasms during bladder testing may benefit from a shortened conservative treatment algorithm or evaluation with the sacral nerve test stimulation to address underlying neurologic etiology.

Principles of Neuromodulation

Neuromodulation may be helpful in patients who are unable to tolerate therapies including anticholinergic medication, who have refractory OAB, or who have coexisting neurogenic conditions. Patients with refractory OAB and concurrent pelvic floor dysfunction including nonobstructive urinary retention and incomplete bladder emptying are ideal candidates. The technique is based on mild electrical stimulation of the pelvic nerves (S3 nerve root) via centrally implanted electrodes in the sacral foramen. Although the exact mechanism of action is incompletely understood, it is postulated that sacral neuromodulation modulates the normal micturition reflex by stimulating the somatic afferent inhibition of sensory processing of the bladder within the spinal cord. This is mediated by unmyelinated C fibers and myelinated A fibers of the pelvic and pudendal nerve roots. Another theory of mechanism is direct inhibitory input to the bladder, which then suppresses bladder overactivity. Concurrent inhibition of the guarding reflex and decrease of pelvic floor specificity also improves nonobstructive urinary retention and dysfunctional voiding.

At this time, the only sacral nerve stimulation device available and US Food and Drug Administration–approved for OAB (urge incontinence and urgency-frequency) and nonobstructive urinary retention is InterStim® Therapy by Medtronic (Minneapolis, MN) (Figure 2). This therapy employs an implanted unilateral lead stimulating the S3 nerve root that is attached to a small pacemaker placed within a subdermal pocket in the buttock region.

Figure 2. *InterStim® Therapy sacral nerve stimulation device (Medtronic, Minneapolis, MN). Photo courtesy of Medtronic.*

InterStim Therapy Sacral Nerve Stimulation Technique

Once it has been decided that the patient is an appropriate candidate for InterStim Therapy, implantation proceeds in 2 steps: a test phase and implantation or lead removal based on test response. The initial test phase may be performed in the office or operating room; full implantation is always performed in the operating room under anesthesia.

Preprocedure patient counseling is critical in reassuring the patient and managing treatment expectations. Many patients have extreme apprehension regarding a needle near the spine or a pacemaker-like foreign body implant. We counsel patients that a small wire will be inserted near the tailbone to modulate or positively affect the nerves causing pelvic floor dysfunction. Although battery implantation following a positive test is discussed, the importance and value of the simple and minimally invasive test phase is stressed. Patients are counseled that approximately 60% of patients undergoing office-based test stimulation and 70% undergoing operating room–based test stimulation will have a positive test response. Response is objectively evaluated by pre- and postvoiding diaries assessing various urinary parameters.

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Office-Based Test Stimulation

Appropriately selected patients may have the first phase of the test stimulation performed in the office. Patients chosen for this test phase must be able to tolerate the procedure with only local anesthesia. Ideal candidates should not be obese, should have OAB without voiding dysfunction, and should not have any significant coexisting medical conditions that would preclude an office-based procedure. This procedure may be facilitated by the availability of office-based fluoroscopy. Various companies are available to provide equipment and qualified personnel on a rental basis.

The patient is brought into the examination room and placed on a table in the prone position. The patient then

has her lower back and gluteal region prepared with betadine and is draped to allow visualization of the lower back and buttocks. Her socks and shoes are removed to allow visualization of the feet. With the use of fluoroscopic guidance with a portable C-arm, the midline of the spine and level of S3 foramen are imaged and skin markings are made. The area is infiltrated with local anesthetic, most commonly 1% lidocaine with epinephrine. A 20-gauge 3.5-inch insulated foramen needle is then inserted into the S3 foramen bilaterally at a 60° angle relative to the skin under fluoroscopic guidance. Once the S3 foramen is located with the foramen needle, a lateral image confirms location and depth in the foramen. The bilateral foramen needles are then stimulated to confirm correct placement in the S3 foramen. Responses signaling correct placement include bellows contraction of the pelvic floor and plantar flexion of the great toe. With the in-office test stimulation, the patient will also be able to confirm correct placement with contraction or tingling of the pelvic floor muscles (eg, rectum, vagina, and perineum). S2 placement will demonstrate plantar flexion of the entire foot with lateral rotation, whereas S4 placement will reveal no lower extremity movement despite bellows response. Once the physician has confirmed correct placement in the S3 foramina bilaterally, temporary test lead wires are passed through the foramen needles and the needles are removed with care given to maintain position of the leads. The temporary test leads with unipolar electrodes are secured to the patient's back with sterile strips and dressing.

The patient is sent home with an external stimulator and instructed on how to use the device. She is given prophylactic dose antibiotics while the temporary test leads are in place. The leads are easily removed in the office once the test phase is complete, typically in 5 to 7 days. Response is assessed by pre- and postprocedure voiding diaries. Patients with a positive test response (50% or more improvement to baseline) are offered full implantation, whereas those with equivocal response undergo operating room–based test stimulation.

Operating Room–Based Test Stimulation

If the patient is not a candidate for office-based test stimulation or did not respond to the in-office test, test stimulation may be performed in the operating room (OR). This procedure is similar to the office-based test, but involves tined quadripolar leads, thus improving lead fixation and test response, and can be performed using intravenous (IV) sedation, local anesthetic, or general anesthesia. If general anesthesia is used, the anesthesiologist is reminded not to use any long-acting muscle relaxants that may impair the ability to stimulate the sacral nerves or visualize their motor response.[11] The patient is given a dose of IV antibiotics preoperatively. Otherwise the procedure begins as described per the in-office test. After the S3 foramen has been identified, the permanent tined lead is passed through the foramen needle. The lead is then exposed and tested in the 0, 1, 2, and 3 positions for response. The sheath is then carefully removed so as not to move the lead and expansion of the tines fix the lead in place. The lead is then tunneled deeply through the subcutaneous fat to a position in the right buttock where the permanent implantable pulse generator (IPG) will be placed in the second stage. The lead is attached to the temporary connector, then tunneled through the subcutaneous fat to an alternative exit site. This is an important step: If the patient were to get a superficial skin infection, the alternative exit site would help prevent the infection from spreading to the location of the permanent IPG and back to the lead. The temporary connector is secured to the patient's back. The patient is taught to use the external stimulator. She tests the lead for 1 week and records response in a voiding diary. We recommend prophylactic antibiotics nightly to prevent infection. After 2 weeks, the patient returns to the OR for either removal of the lead or implantation of the IPG, depending on response.

Implantation

After a successful test phase, the patient is brought to the OR for implantation of the battery or implantable generator (IPG). The patient is placed in the prone position and prepared and draped sterilely. She receives a dose of perioperative IV antibiotics. If the first phase was done in the OR and there is preexisting placement of the permanent quadripolar lead, the implant stage is quick and does not require fluoroscopy. The previous incision where the temporary connector was placed in the buttock is opened. The permanent IPG is then connected to the lead and buried in a deep subcutaneous pocket in the right buttock. Intraoperative assessment of the IPG is recommended prior to closure of the incision.

If the first test stimulation was done in the office, fluoroscopy is required to place the permanent lead. The quadripolar tined lead is inserted in a similar fashion on the side where the patient had the best in-office test response. The lead is then tunneled deeply through the subcutaneous fat to an incision in the buttock region. It is attached to the IPG and buried in the deep subcutaneous pocket.

Results and Complications

InterStim Therapy outcomes are based on a positive test stimulation that

then results in long-term but reversible implantation. Siegel and colleagues[12] have reported long-term success rates in patients with chronic, debilitating symptoms of overactive bladder and voiding dysfunction. This multicenter, prospective study followed patients at regular intervals with outcome data. Patients were observed from 1.5 to 3 years postimplantation. Results demonstrated that, after 3 years, 59% of 41 urge incontinent patients continued to have significant improvement, with 46% of the patients being completely dry. After 2 years, 56% of the urgency-frequency patients continued to show greater than 50% reduction in micturition frequency. After 1.5 years, 70% of 42 retention patients continued to show greater than 50% reduction in catheter volume per catheterization.[12]

Based on a 5-year, prospective, multicenter trial evaluating the long-term safety and efficacy of sacral nerve neuromodulation in patients with refractory urge incontinence, van Kerrebroeck and coworkers[13] reported on 152 patients in 17 centers worldwide undergoing implantation. Ninety-six had urge incontinence, 25 had urgency-frequency, and 31 had retention. Voiding diaries were collected annually for 5 years. At 5 years after implantation, 68% of patients with urge incontinence, 56% with urgency-frequency, and 71% with retention continued to have successful outcomes based on 50% or greater improvement from baseline.

Based on a systematic review of published studies, Brazzelli and colleagues[14] reported on 4 randomized, controlled trials and 30 case series involving approximately 120 patients. Eighty percent achieved continence or greater than 50% improvement in their incontinence symptoms after sacral neurostimulation, compared with 3% of controls receiving conservative therapies while awaiting the implant. Benefits were reported to persist 3 to 5 years after implantation. The overall reoperation rate was 33%, with the most common reason for surgical revision being pain or infection at the IPG site. Common complications were pain at the implant site in 25% of patients, lead migration in 16%, wound complications in 7%, adverse affect on bowel function in 6%, and generator problems in 5%. Permanent removal of the electrodes was reported in 9% of patients. However, their review, especially with regard to complications, was based on the original cutdown technique that required a large incision for implantation of the lead. Since the introduction of the percutaneous approach described above, complications have significantly reduced.[14]

InterStim Therapy may also have a role in refractory overactive bladder symptoms following stress incontinence surgery. Sherman and colleagues[15] reported that 22 of 34 patients (65%) within this subgroup responded to test stimulation and underwent permanent implantation with improvement in their symptoms. The same group also assessed factors associated with cure rates and concluded that age greater than 55 years and presence of more than 3 chronic conditions were independent factors associated with a lower cure rate in patients undergoing implantation.[16]

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Although currently approved only for urge incontinence, urgency-frequency, and nonobstructive urinary retention, InterStim Therapy is being investigated for other neurogenic pelvic floor disorders, including chronic pelvic pain, interstitial cystitis, fecal incontinence, irritable bowel syndrome, and chronic constipation. Further investigation is required to determine if InterStim Therapy is safe and effective for these indications.

Success of this therapy is based on the hypothesis that most pelvic floor dysfunction has a neuropathic etiology that responds poorly to pharmacotherapy and surgical intervention. Studies suggest the therapy is associated with minimal risk/side effects and significant success rates compared with traditional therapies. A unique feature of this therapy is the minimally invasive test phase that is used to accurately and adequately assess patient response prior to proceeding with implantation.

Conclusion

The diagnosis of overactive bladder is increasing with growing public awareness and an aging population. The practicing ob-gyn will most likely see more of these patients seeking improved quality of life. Evaluation and treatment of overactive bladder is straightforward and effective. Although some patients will respond to conservative treatments, for those patients who are refractory to traditional therapy, are unable to tolerate medications, or have coexisting neurogenic conditions or pelvic floor dysfunction, InterStim Therapy sacral neurostimulation may be an option. The procedure, based on a minimally invasive in-office test stimulation, is safe and effective with good long-term efficacy.

Future directions may advocate this proven treatment approach for a variety of additional pelvic floor conditions that have previously had suboptimal treatment results. Further data are required for these expanding indications. In the meantime, the practicing clinician should be aware of this treatment option in counseling and managing patients with overactive bladder and urinary retention. ■

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Main Points

- Overactive bladder is defined by the International Continence Society as urgency, with or without urge incontinence, usually with frequency and nocturia in the absence of local or metabolic factors explaining these symptoms.
- Most women express dissatisfaction with currently available overactive bladder (OAB) treatments and their side effects.
- Diagnosis of OAB is made in the office through patient history, physical examination, and basic bladder testing.
- Although anticholinergic medication may help some patients, recent studies have shown long-term compliance is suboptimal due to variable success rates and poor tolerability. Neuromodulation may be helpful in patients who are unable to tolerate therapies including anticholinergic medication, who have refractory OAB, or who have coexisting neurogenic conditions.
- At this time, the only sacral nerve stimulation device available and US Food and Drug Administration–approved for OAB, urge incontinence, urgency-frequency, and nonobstructive urinary retention is InterStim® Therapy by Medtronic (Minneapolis, MN). This therapy employs an implanted unilateral lead stimulating the S3 nerve root that is attached to a small pacemaker placed within a subdermal pocket in the buttock region.
- Sacral nerve stimulation is safe and effective with good long-term efficacy. Future directions may advocate this novel treatment approach for a variety of additional pelvic floor conditions that have previously had suboptimal treatment results, but further data are required for these indications.